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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,990	08/09/2001	Charles Joel Arntzen	P00245USG	5525

22885 7590 09/26/2003

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801 GRAND AVENUE
SUITE 3200
DES MOINES, IA 50309-2721

EXAMINER

ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/26/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,990

Applicant(s)

ARNTZEN ET AL.

Examiner

Robert A. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-78 is/are pending in the application.
- 4a) Of the above claim(s) 76-78 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 73-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that no separate search is required for the non-elected group. This is not found persuasive because searches of the various inventions would not be coextensive in scope.

The requirement is still deemed proper and is therefore made FINAL.

Claims 73-78 are pending. Claims 76-78 are withdrawn from consideration as being drawn to non-elected inventions. Claims 73-75 are currently under examination.

Information Disclosure Statement

The Information Disclosure Statement filed on 10-4-2001 (Paper No. 2) is acknowledged. An initialed copy is attached hereto. It should be noted that all of the cited references were not available and hence were not considered. Said references will be considered when they become available. Applicant is invited to provide copies of the missing references in order to expedite their consideration.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the date of execution for the signature of Inventor Arntzen is missing.

Claim Objections

Claims 74 and 75 are objected to because of the following informalities: Claims 74 and 75 recite the phrases "said plant is tomato" and "said plant is potato". Said phrasing, while interpretable, could be confusing. It is suggested that the aforementioned phrases be changed to "said plant is a tomato plant" and "said plant is a potato plant".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 73 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of U.S. Patent No. 5,612,487. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in U.S. Patent No. 5,612,487 for the production of a hepatitis B viral surface antigen in transgenic plants would render the claimed invention of the instant application obvious since they both recite the same goals and the same basic method steps.

Claims 73-75 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-11 of U.S. Patent No. 6,034,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in U.S. Patent No. 6,034,298 for the production of a Transmissible Gastroenteritis virus antigen in transgenic plants would render the claimed invention of the instant application obvious since they both recite the same goals and same basic method steps.

Claims 73-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48-51 and 56 of copending Application No. 09/918,937. Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims are drawn to methods of producing a vaccine comprising a viral antigen comprising the steps of constructing a plasmid, transferring said plasmid to said plant and expressing said the encoded viral antigen in said plant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 73 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 73 of copending Application No. 09/816,846. Although the conflicting claims are not identical, they are not patentably distinct from each other because all claims are drawn to methods of producing a viral antigen (i.e. vaccine/immunogen) in transgenic plants.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 73-74 are rejected under 35 U.S.C. 102(b) as anticipated by Goodman et al. (WO 87/00865 – IDS-2).

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen

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from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato plant.

Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotropic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see page 8, lines 3-8). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see page 3, line 5 to page 7, line 4); transferring said plasmid vector to the plant cell (see page 7, lines 5-33); the regeneration of said plant from the transformed cells (see page 9, lines 15-21); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see page 9, lines 21-25); and the purification of said antigen protein (see page 9, lines 27-31). Consequently, Goodman et al. anticipate all the limitations of the rejected claims.

102(e)
Claims 73-74 are rejected under 35 U.S.C. 102(e) as anticipated by Goodman et al. (U.S. Patent 4,956,282 – IDS-2).

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen

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from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato plant.

Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotropic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see column 3, lines 30-35). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see column 4, lines 58-62). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see column 2, line 10 to column 4, line 18); transferring said plasmid vector to the plant cell (see column 4, lines 19-48); the regeneration of said plant from the transformed cells (see column 5, lines 34-40); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see column 5, lines 39-42); and the purification of said antigen protein (see column 5, lines 46-50). Consequently, Goodman et al. anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (WO 87/00865 – IDS-2).

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato or a potato plant.

Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotropic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see page 5, lines 1-3 and lines 21-26). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see page 8, lines 3-8). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising

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the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see page 3, line 5 to page 7, line 4); transferring said plasmid vector to the plant cell (see page 7, lines 5-33); the regeneration of said plant from the transformed cells (see page 9, lines 15-21); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see page 9, lines 21-25); and the purification of said antigen protein (see page 9, lines 27-31). Goodman et al. differs from the claimed invention in that they do not explicitly disclose the use of potato plants as the recipients of the plasmid vector. However, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see page 8, lines 3-8) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanacai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference. One of skill in the art would have had a high expectation of success since potato plants are very similar to the disclosed tomato and tobacco plants. Moreover, Goodman et al. disclose that the recombinantly expressed protein could be found in plant parts such as tubers (see page 8, lines 9-11).

Claim 75 is rejected under 35 U.S.C. 103(a) being unpatentable over Goodman et al. (U.S. Patent 4,956,282 – IDS-2).

The instant claims are drawn to a method of producing a vaccine comprising constructing a plasmid vector or DNA fragment comprising a DNA sequence encoding a viral antigen coupled to a plant functional promoter, transferring said vector or DNA fragment into a plant cell, regenerating a transgenic plant from said plant cell, obtaining the expressed viral antigen

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from a harvested portion of said transgenic plant and purifying said antigen. Said transgenic plant can be a tomato or a potato plant.

Goodman et al. disclose the use of transgenic plants to express recombinant viral antigen proteins from leukemia and lymphotropic retroviruses, herpes simplex virus, hepatitis B virus and adenovirus (see column 3, lines 30-35). Goodman et al. further disclose the use of tomato plants, as well as other edible plants, to express said proteins (see column 4, lines 58-62). The methodology disclosed by Goodman et al. comprises: constructing a plasmid vector comprising the polynucleotide encoding the protein (viral antigen) coupled to a promoter that is functional in the plant host (see column 2, line 10 to column 4, line 18); transferring said plasmid vector to the plant cell (see column 4, lines 19-48); the regeneration of said plant from the transformed cells (see column 5, lines 34-40); the harvest of the plants or plant parts to obtain the expressed viral antigen protein (see column 5, lines 39-42); and the purification of said antigen protein (see column 5, lines 46-50). Goodman et al. differs from the claimed invention in that they do not explicitly disclose the use of potato plants as the recipients of the plasmid vector. However, since Goodman et al. disclose the use of tomato and tobacco plants to express said proteins (see column 4, lines 58-62) and tomato, potato and tobacco plants are all members of the same phylogenic family (*Solanacai*), the use of potato plants merely constitutes an obvious variation of the method disclosed in the cited reference. One of skill in the art would have had a high expectation of success since potato plants are very similar to the disclosed tomato and tobacco plants. Moreover, Goodman et al. disclose that the recombinantly expressed protein could be found in plant parts such as tubers (see column 4, lines 60-62).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Robert A. Zeman
September 23, 2003